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10/757,355	01/14/2004	Matthias Blau	BLAU	3324
20151	7590	08/10/2006	EXAMINER	
HENRY M FEIEREISEN, LLC 350 FIFTH AVENUE SUITE 4714 NEW YORK, NY 10118			LUSTUSKY, SARA	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,355

Applicant(s)

BLAU ET AL.

Examiner

Sara Lustusky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 22-33, 35-41, 42 and 43 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to because there are dark regions, the details of which are not easily distinguishable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.
4. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
5. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claim 38:

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- a. Recites the limitation "the oval window" in line 3. There is insufficient antecedent basis for this limitation in the claim.
- b. Recites the limitation " a second other end " in line 4. This limitation implies that there is a first other end. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. **Claims 22, 38 and 43** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
11. Claim 22 positively claims a part of the body in line 6. The recitation "coupled to the ear" in line 6 should read - - adapted to be coupled to the ear - -.
12. Claim 38 positively claims a part of the body in lines 2 and 3. The recitation "the thin shell is coupled to the articular cartilage" should read - - the thin shell is adapted to be coupled to the articular cartilage - -.
13. Claim 43 positively claims a part of the body in line 3. The recitation "the other end being connected with a bone" should read - - the other end being adapted to connect with a bone - -.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

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form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. **Claims 22- 29, 32-33 and 37-41** are rejected under 35 U.S.C. 102(b) as being anticipated by Ball et al. (PGPUB 2001/0003788 A1).

16. **Claim 22:** Ball et al. teaches an implantable electromechanical converter (100) comprising: a hermetically sealed hollow body (10, 320, 340, 360) made of a biocompatible material, said hollow body (10, 320, 340, 360) having a thin shell with an exterior side coupled to the ear ossicle and an interior side (as described in lines 3-12 of paragraph [0082]); at least one piezoelectric converter element housed in the hollow body and coupled the interior side of the thin shell (as described in lines 4-10 of paragraph [0122]), and a stable edge supporting the thin shell, said stable edge being coupled to a counter-support in the middle ear space (as described in lines 4-10 of paragraph [0081]).

17. **Claim 23:** Ball et al. teaches the converter of claim 22, as described above, wherein the stable edge is taught as being generally a cylindrical shape (as described in lines 6-8 of paragraph [0082]), which the examiner considers to include elliptical shapes.

18. **Claim 24:** Ball et al. teaches the converter of claim 22, as described above, wherein the hollow body includes a means for limiting an excursion of the thin shell (as described in paragraphs [0124] and [0125]).

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19. **Claim 25:** Ball et al. teaches the converter of claim 22, as described above, wherein the biocompatible material of the hollow body comprises titanium or a titanium alloy (as described in lines 3-4 of paragraph [0125]).

20. **Claim 26:** Ball et al. teaches the converter of claim 22, as described above, wherein the thin shell is formed as a plate (as seen in embodiment in Figure 4), the hollow body (10) having a diameter of 1mm and a thickness of 1mm (as described in lines 16-18 of paragraph [0091]), and therefore inherently the thin shell may have a thickness of a range including thicknesses between 20 and 50 micrometers.

21. **Claim 28:** Ball et al. teaches the converter of claim 22, as described above, wherein the thin shell and the stable edge are formed as a single piece and are shaped by a mechanical separation or forming process or an etching process (as described in lines 3-4 of paragraph [0125]).

22. **Claim 29:** Ball et al. teaches the converter of claim 22, as described above, wherein the at least one piezoelectric converter element (308, 310, 326, 328) (as seen in Figures 13 and 15a, 15b) comprises an element selected from the group consisting of a piezoelectric ceramic material, a piezoelectric film, and a piezoelectric single crystal (as described in lines 8-10 of paragraph [0122]).

23. **Claim 32:** Ball et al. teaches the converter of claim 22, as described above, wherein the at least one piezoelectric converter element (308, 310, 326, 328) is mechanically supported on the interior side of the thin shell of the housing (302) (as seen in Figures 13 and 15a, 15b).

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24. **Claim 33:** Ball et al. teaches the converter of claim 22, as described above, wherein the at least one piezoelectric converter element is implemented as unimorphic or multimorphic bending plate or bending beam (308, 310, 326, 328) (as seen in Figures 13 and 15a, 15b) (as described in lines 8-10 of paragraph [0122]).

25. **Claim 37:** Ball et al. teaches the converter of claim 22, as described above, wherein the thin shell is coupled to the articular cartilage of the severed incus-stapes joint that is coupled with the long incus appendage (as seen in the embodiment of Figures 7 and 9).

26. **Claim 38:** Ball et al. teaches the converter of claim 22, as described above, and further comprising a post (40, 40c) made of a biocompatible material (as described in the embodiment in lines 1-2, 7-9 and 12-14 of paragraph [0104]), said post (40, 40c) forming a counter-support which is supported on a first end in a recess of the oval window (EE) (for purposes of examination the examiner considered "the oval window" to mean reference character "6" as seen in Figure 2 of the Drawings) and is configured on a second other end to receive the stable edge (as seen in the embodiments in Figures 8 and 9).

27. **Claim 39:** Ball et al. teaches the converter of claim 38, as described above, wherein the post (40, 40c) includes a means for anchoring the post in a bone canal of the stapes tendon (as seen in Figures 8 and 9).

28. **Claim 40:** Ball et al. teaches the converter of claim 38, as described above, wherein the post (40, 40c) includes positioning means for positioning the thin shell

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relative to the coupled ear ossicle (as described in lines 8-11 of paragraph [0104]) (as seen in Figures 8 and 9).

29. **Claim 41:** Ball et al. teaches the converter of claim 40, as described above, wherein the positioning means are implemented as insertable support plates or wedges made of a biocompatible material (as described in the embodiment in lines 1-2, 7-9 and 12-14 of paragraph [0104]) which are inserted between the post (40, 40c) and the stable edge (as seen on each end of 40 and 40c in Figures 8 and 9).

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. **Claim 27** is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ball et al. (PGPUB 2001/0003788 A1).

32. Ball et al. teaches the converter of claim 22, as described above, wherein the thin shell and the stable edge are formed as a single piece. While Ball et al. does not expressly teach that the thin shell and the stable edge are welded together, it would have been obvious to one of ordinary skill in the art at the time of the invention to weld a

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connection between the thin shell and the stable edge as this is an obvious variant in the art to the process of machining and would produce an equivalent product.

33. **Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ball et al. (PGPUB 2001/0003788 A1) in view of Wang et al. (Patent 6627104 B1).

34. Ball et al. teaches the converter of claims 22 and 29, as described above, comprising a hollow body having a thin shell, coupled to an ossicle and at least one piezoelectric converter element housed in the hollow body. Ball et al. teaches that the piezoelectric converter element may be made of any piezoelectric material, however materials PZN-PT and PMN-PT were not expressly taught.

35. Wang et al. teaches the use of piezoelectric materials for use in electronic and microelectronic devices, the materials taught include lead zinc niobate-lead titanate (PZN--PT) or lead magnesium niobate-lead titanate (PMN--PT) (as described in lines 41-55 of column 1).

36. It would have been obvious to one of ordinary skill in the art at the time of the invention to make a piezoelectric converter element similar to that taught by Ball et al. from PMN-PT or PZN-PT as taught by Wang et al. The materials taught by Ball et al. can be substituted with the materials taught by Wang et al. as a design choice because they have similar piezoelectric properties (as described in lines 41-55 of column 1 of Wang et al.).

37. **Claim 31** is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ball et al. (PGPUB 2001/0003788 A1).

38. Ball et al. teaches the converter of claim 22, as described above, wherein the at least one piezoelectric converter element is secured within the thin shell (as described in lines 8-9 of paragraph [0128]).

39. While Ball et al. teaches that the at least one piezoelectric converter element is secured; it is not expressly taught that the piezoelectric converter element is secured by adhesive. However, securing means are taught which include adhesive (as described in lines 4-14 of paragraph [0081]).

40. It would have been obvious to one of ordinary skill in the art at the time of the invention to secure the piezoelectric converter element using adhesive in view of the teachings of Ball et al. because the piezoelectric converter element works by deformation and thus requires at least a portion to be braced to provide a resistive force against which to deform. In view of the teachings of Ball et al., adhesive can be used to secure the piezoelectric converter element to provide a resistive force.

41. **Claims 35 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ball et al. (PGPUB 2001/0003788 A1) in view of Berrang et al. (PGPUB 2002/0019669 A1).

42. Ball et al. teaches the converter of claim 22, as described above, comprising a hollow body having a thin shell, and at least one piezoelectric converter element housed

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in the hollow body, and electric wires (24) extending through a feedthrough (26) to connect to provide an external connection to the electrical voltage (as described in the embodiment of lines 13-15 of paragraph [0097]), but does not teach that the feedthrough is electrically insulated.

43. Berrang et al. teaches an implantable electronic device comprising sealed, electrically insulating feedthroughs, wherein the insulating materials include a material selected from the group consisting of glass, ceramics and minerals (as described in lines 1-5 of paragraph [0023] and lines 1-2 and 4-6 of paragraph [0079]).

44. It would have been obvious to one of ordinary skill in the art at the time of the invention to insulate the sealed feedthroughs of a device similar to that taught by Ball et al. with insulating materials similar to those taught by Berrang et al. because it is commonly known in the art that implantable electrical components should be insulated to protect the device and to protect the patient and that glass, ceramics and minerals are commonly used insulating materials known in the art.

45. **Claims 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ball et al. in view of Bushek et al. (Patent 5836863).

46. Ball et al. teaches the converter of claims 22 and 38-40, as described above, comprising a hollow body having a thin shell, and at least one piezoelectric converter element housed in the hollow body, which is coupled to an ossicle and has a counter support, which is taught as a post in an alternative embodiment. While Ball et al. teaches various mounting mechanisms, including screws and a support element having

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two ends, it is not expressly taught that these mechanisms are combined, or that the post comprises two segments.

47. Bushek et al. teaches a piezoelectric converter element (115, 120) with a counter-support (110) having two ends, with one end being connected with the stable edge and the other end being connected with a bone by a screw (130) connection (as seen in Figures 1A, 1B, 2 and 3). Bushek et al. also teaches that the counter support may be in the form of a post comprising two segments that are adapted to be lockably engaged (as seen in Figures 4A, B, C and 5A, B, C).

48. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine supports similar to those taught by Ball et al. to form a counter-support similar to that as taught by Bushek et al. to support a piezoelectric converter element similar to that of Ball et al. because it is a functional equivalent that provides variety for dealing with different patient anatomies and different ossicle or middle ear defects (as described in lines 9-10 and 35-45 of column 7 of Bushek et al.).

Allowable Subject Matter

49. **Claim 34** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

50. Claim 34 is allowable over the prior art of record because none of the prior art of record shows an electronic circuit located inside a sealed hollow body with a piezoelectric converter element.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Maniglia et al. (Patent 5558618) shows a relevant mounting mechanism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S.L.


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